IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR ENTRY OF A *LONE PINE* CASE MANAGEMENT ORDER

I. Relevant Factual Background and Procedural History

A. Events Triggering This Litigation

On April 25, 2008, Actavis Totowa LLC initiated a nationwide Class I recall of both dosages of Digitek® due to the *possibility* that tablets with approximately double the specified thickness (and conceivably twice the approved level of active ingredient) may have been commercially released. The recall was initiated after nonconforming tablets were observed in one lot of the 0.125 mg tablets manufactured – Lot 70924A, manufactured in November 2007. The small number of larger-than-normal tablets were observed before shipment of Lot 70924A, and two comprehensive inspections followed. First, the entire lot, consisting of approximately 4.8 million tablets, was visually inspected pursuant to a protocol drafted by the Quality Assurance Department. Actavis discovered a total of 20 (0.00041%) nonconforming tablets. The lot was then subjected to a second, rigorous sampling inspection, in which no nonconforming tablets were found. Ultimately, Lot 70924A was released for distribution on January 28, 2008, and sent to Mylan Pharmaceuticals, Inc. for distribution in early February 2008. The April 25, 2008 recall included *all* lots then in distribution, regardless of dose strength, and even though there was no evidence of any other nonconforming tablets.

No Plaintiff's counsel in any Digitek® case in any jurisdiction has produced a double thick tablet or provided test results from a certified lab that a tablet, within the expiry date, was out of specification. Indeed, Plaintiffs' counsel in the New Jersey cases made this admission on the record at a hearing before Judge Harris on March 27, 2009 attached as Exhibit 1. Further, this fact has been discussed at a number of in-chamber conferences with this Court. It has become increasingly clear that the publicity of the recall and aggressive advertising in follow-up to the recall is at the root of this litigation, not actual evidence of ingestion of a defective product.

B. Proof of Digoxin Toxicity Is a Required Element of Proof In Every MDL Case

It is axiomatic that in a product liability case a plaintiff must prove (1) a product defect; (2) injury; (3) proximately caused by the defective product. As a baseline, each Plaintiff must prove that he or she received too much digoxin and became toxic. Nonetheless, responses to Requests for Admission served by various Plaintiffs have revealed that many Plaintiffs' counsel had no medical records in their possession when they filed suit that established high digoxin levels. In even more cases (likely over a majority) there is simply no evidence of digoxin toxicity reflected by the medical records collected to date by a third party collection service since the inception of the lawsuit. See Exhibit 2 which contains a number of case summaries prepared by a licensed physician working for Tucker Ellis & West LLP. Indeed, as noted below, many of the cases reflect obvious, unrelated alternative causes for the injuries or deaths alleged by plaintiffs.[2] Many cases show serum digoxin levels that are squarely within the therapeutic level and exactly what a medical

[2] Marian Metzler's death certificate indicates she died as a result of a hip fracture. Sarah Hood's indicates she died of end stage cardiovascular disease. Arnold Newsome's indicates he died of a gastrointestinal bleed and profound anemia.

professional would hope to see given the use of a conforming product.[3] Other cases reveal no injury whatsoever.[4] None reflect digoxin toxicity.

C. Brief Procedural History Relevant to Pending Motion.

PTO #16 establishes the procedure for completion of Fact Sheets. The Court is well aware of the significant difficulties and inordinate delays in the submission of these fact sheets and the various extensions requested by Plaintiffs with respect to PTO #16's trial group selection process. See letter of June 2, 2009, Exhibit 3 and letter of June 5, 2009 Exhibit 4 setting forth this history in detail.

Defendants submitted requests for admission to approximately 39 plaintiffs in follow-up to the Fact Sheet inquiring as to what records they had in their possession at the time of filing suit. Plaintiffs objected to these requests and in PTO #39, Judge Stanley overruled the objections and ordered Plaintiffs to answer them.

D. Many Plaintiffs Have Filed Suit Without Having Possession of Any Medical Records

Plaintiffs' responses to those requests for admission are now being served. They show repeated instances of filings without having any medical records in hand. For example, the firm of Morgan & Morgan in Florida recently submitted their responses to Requests for Admission in a number of cases. Those responses are attached at Exhibit 5. In brief, they establish that Plaintiffs' counsel had only the following information when the complaints were filed:

1. Elwood Bull – A recall notice, some copies of prescriptions, and a one page summary of medical expenses. No medical records.

2. Raymond Gary – Only prescription records and recall notices. No medical records.

[3] See cases of Helen Gilmore, Montez Green, Donald Earl Butts, Arnold Newsome and Karen Collier.
[4] See summaries of Alice Maroon and Eva Mae McCarty.

3. Jessie Hickman – A medication list. No medical records.

4. Shirley Hurley –Recall letter and a photocopy of prescription bottles. No medical records.

5. Geneva Richmond – Recall letter, photocopy of prescription bottle, and a death certificate. No medical records.

6. Shirley Williams – Recall letter and prescription records. No medical records.

In *Carolyn Hebert v. Actavis,* Plaintiff's counsel admitted that they did not review any medical records before filing suit – they only had a recall letter when they filed. See Exhibit 6. Medical records have subsequently been obtained by a third party provider which demonstrate no digoxin toxicity. See Exhibit 7. Similarly, in two cases – *Deborah Figuerora, Personal Representative of the Estate of James Hammer* and *Rosetta Hicks, Personal Representative of the Estate of Henrietta Hicks* - Plaintiffs' counsel admitted that they only had death certificates in their possession at the time of filing; again, no medical records. See Exhibit 8. The death certificates are attached to this motion. It is clear that they provide no basis to conclude that digoxin toxicity was responsible for the deaths of these plaintiffs. See Exhibit 9.

E. In Cases Where Medical Records Were Submitted With Fact Sheets or Have Been Subsequently Obtained Many, If Not A Majority, Reflect No Evidence Of Digoxin Toxicity.

To be sure, some Plaintiffs submitted medical records with their Fact Sheets. But, in a very large number of those cases, the records do not reference an elevated digoxin level or any clinical diagnosis or suspicion of digoxin toxicity. In cases where no medical records were submitted with the fact sheets, a third party service has obtained medical records showing the same deficiencies.

For example, the trial case of Dephlia Davis has been dismissed by Plaintiff, for good reason. There were no elevated digoxin levels and no suggestion of digoxin toxicity. See Exhibit 2. This case was presumably filed because Mr. Davis, the decedent, was taking a product that was recalled and he died. Even a cursory review of the records shows no digoxin toxicity. There are

many other cases with no such evidence. Exhibit 2. This Exhibit is only a representative sampling of cases without such evidence.

II. Argument

The facts demonstrate that many of the cases pending in the MDL were filed without a shred of evidence that the plaintiffs experienced digoxin toxicity. Further, subsequent collection of medical records have failed to produce evidence that can establish this baseline burden of proof. In light of these facts, this Court should issue a *Lone Pine* Order requiring an affidavit from a medical expert in each case establishing that there is medical evidence of digoxin toxicity. There is abundant legal authority to do so, and Defendants seek a narrow and focused order.

A. This Court Has Broad Authority to Issue a *Lone Pine* Order That Will Promote Efficiency.

A *Lone Pine* order is a valuable and often necessary case management tool in pharmaceutical multidistrict litigation. *See In re Vioxx Prods. Liab. Litig.*, MDL NO. 1657, Pretrial Order No. 28, at § II.A.8 (E.D. La. Nov. 9, 2007); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, MDL No. 1699, Pretrial Order No. 29 (N.D. Cal. Aug. 1, 2008); *In re Rezulin Prods. Liab. Litig.*, MDL No. 1348 Pretrial Order No. 370 (S.D.N.Y. May 9, 2005); *In re Baycol Prods. Liab. Litig.*, MDL No. 1431, Pretrial Order No. 114 (D. Minn. Mar. 18, 2004). A *Lone Pine* order requires plaintiffs to provide some evidence of certain elements of their claims, e.g. medical causation, in the form of affidavits or expert reports to support a credible claim. *See Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598, 604 n.2 (5th Cir. 2006) (citing *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000)). "The basic purpose of a *Lone Pine* order is to identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants." *Baker v. Chevron USA, Inc.*, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007); *In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008). Separating potentially

meritorious claims from unfounded claims avoids the burdensome workup of meritless claims, reduces litigation expenses, and conserves judicial resources. *See Abbatiello v. Monsanto Co.*, 569 F. Supp. 2d 351, 354 (S.D.N.Y. 2008) (requiring early case-specific expert affidavits protects the Court and Defendants from burdensome non-meritorious claims and merely requires that plaintiffs provide information that they should have had before filing their claims). *Lone Pine* orders are consistent with the purpose of MDL consolidation to enhance the efficiency and consistency of the pretrial phase of the pending cases consolidated into the MDL. *See, e.g., Judy v. Pfizer, Inc.*, 2005 WL 2240088, at *3 (E.D. Mo. Sept. 14, 2005). Courts have wide discretion to issue *Lone Pine* orders under Federal Rule of Civil Procedure 16. *See Acuna*, 200 F.3d 335, 340 (5th Cir. 2000).

B. Imposition of a *Lone Pine* Order in the Digitek® MDL Would Not Unduly Burden Plaintiffs Because The Order Is Narrowly Focused and Requires Plaintiffs to Establish Now What They Would Eventually Have to Prove.

Entry of this proposed *Lone Pine* order will not unduly burden plaintiffs. Individual Plaintiffs will need to present this evidence to support their case. And they should have already collected his information. *See Acuna*, 200 F.3d at 340 ("Each plaintiff should have had at least some information regarding the nature of his injuries, the circumstances under which he could have been exposed to harmful substances, and the basis for believing that the named defendants were responsible for his injuries.").

Additionally, Defendants' proposed *Lone Pine* order is relatively limited compared to other more exhaustive *Lone Pine* orders: Defendants' proposed order merely requires plaintiffs to file an expert affidavit describing the basis for believing that the Digitek® user experienced digoxin toxicity and identifying the medical records the expert relied upon. To prevail in any individual case, a Plaintiff would have to prove: (1) that he or she received defective Digitek® tablets in sufficient quantity to result in digoxin toxicity; and (2) prove specific causation between such

defective tablets and any injury they claim. As part of that specific cause analysis, a Plaintiff would have to, out of necessity, rule out a number of co-morbidity factors that might just as easily explain digoxin toxicity. Defendants' requested relief does not require Plaintiffs to offer Affidavit evidence relating to defect, nor does it obligate them to offer an Affidavit ruling out co-morbidities. At this time, Defendants only seek an Order requiring Plaintiff to establish one critical part of their case – that there is reliable medical evidence that they exhibited digoxin toxicity either by elevated serum digoxin levels or clinical diagnosis. *Cf. Grant v. E.I. DuPont De Nemours & Co.,* 1993 WL 146634, at *4 (E.D.N.C. Feb. 17, 1993) (issuing *Lone Pine* order requiring plaintiffs to provide expert medical opinions that rule out other causes); *Cottle,* 3 Cal. App. 4th at 1372 (issuing *Lone Pine* order requiring plaintiffs to identify (1) the toxic substance; (2) date or dates of exposure; (3) method of exposure; (4) nature of plaintiff's injury; and (5) each medical expert who would support the plaintiff's personal injury claims). If a claim is meritorious, this requirement should be rather easy to satisfy. If plaintiffs have no medical records to support digoxin toxicity then they had no factual basis to file the action in the first place and have no basis to continue their action. Finally, the order should not be directed to the trial selected cases so those counsel are not burdened with complying with the court ordered affidavit.

C. Defendants' Proposed *Lone Pine* Case Management Order Will Promote Efficiency in the Digitek® MDL.

This Court has an interest in controlling its docket to eliminate cases that are clearly without merit. Further, depletion of insurance proceeds by defense costs incurred by defending meritless cases is an interest that all parties and this Court should recognize. While Rule 11 is a mechanism available to Defendants, the cost of determining each meritless claim on a case by case basis is staggering. The parties have retained RecordTrak to obtain medical records. To date, RecordTrak has billed Defendants over $75,000 to obtain records and this figure will soon exceed $100,000. As

indicated above, many of these records show no digoxin toxicity. Defendants are spending money and resources to evaluate these cases, collect records and analyze records which only ultimately serve to prove that these cases should never have been filed. Absent the entry of a *Lone Pine* order, judicial resources will be expended considering numerous Rule 11 motions filed by Defendants in individual cases addressing the Plaintiffs' basic failure to conduct pre-filing factual investigation.

D. The FDA Conclusion About The Small Likelihood of Harm Strongly Supports Entry of a Lone Pine Order.

While the record collection process and evaluation described above has been underway, the FDA determined that there is a small likelihood that any recalled Digitek® caused injury to anyone. (*See* July 8, 2009 FDA Letter, attached as Exhibit 10.) *Lone Pine* orders are especially appropriate where a governmental agency determines that causation is unlikely and the risk of injury small. *See Cottle v. Superior Court of Ventura County*, 5 Cal. Rptr. 2d 882, 3 Cal. App. 4th 1367, 1372 (Cal. Ct. App. 1992) entering a Lone Pine Order, and (noting that the California Department of Health Services issued remedial and final reports concluding that the waste materials at issue do not pose any significant threat to the health of the plaintiff or the environment); *Lore v. Lone Pine*, 1986 WL 637507, at *1 (N.J. Super. Ct. Nov. 18, 1986) (entering order, noting that EPA reports indicated that there was no groundwater contamination or transport of pollution in contradiction to plaintiffs' complaint).

CONCLUSION

In light of the medical records produced to date and the FDA's determination, a *Lone Pine* case management order is necessary to help the parties and the Court "weed out" deficient claims, focus on the cases that have arguable merit, and deter future filing of claims for which plaintiffs will be unable to present *prima facie* evidence of digoxin toxicity. Cases not selected in Trial Group 1

should not be permitted to stand idle in hope of an eventual nuisance settlement when so many lack merit.

For the foregoing reasons, Defendants respectfully move this Court for entry of a *Lone Pine* case management order applicable to all cases pending in the Digitek® MDL, as well as all cases transferred to or filed within the MDL going forward.

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CERTIFICATE OF SERVICE

I hereby certify that on September 10, 2009, a copy of the foregoing Motion for Entry of a *Lone Pine* Case Management Order was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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